IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC.,	:	ELECTRONICALLY FILED
	:	
Plaintiff	:	
	:	Civil Action No. 1:05-CV-1416
v.	:	(Judge Rambo)
	:	
MERCK & CO., INC.,	:	
	:	JURY TRIAL DEMANDED
Defendant	:	

DECLARATIONS IN SUPPORT OF DEFENDANT'S REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT

Dated: October 26, 2005

Respectfully submitted,

s/ Brian P. Downey

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Justin G. Weber (PA 89266)
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Mary J. Morry (NJ 015351990)
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Fax: (732) 594-5301

Attorneys for Defendant

TABLE OF DECLARATIONS

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA
HARRISBURG DIVISION

MYLAN PHARMACEUTICALS INC., Plaintiff,	)	
v.	)	Civil Action No. 05-cv-1416 (Judge Rambo)
MERCK & CO., INC., Defendant.	)	

DECLARATION (II) OF MARY J. MORRY UNDER 28 U.S.C. § 1746 IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

I, Mary J. Morry, declare under penalty of perjury that:

1. I am the same Mary J. Morry who made a declaration dated August 25, 2005 that was submitted with the motion of Defendant, Merck & Co., Inc. ("Merck") to dismiss plaintiff's complaint for declaratory judgment.

2. Plaintiff Mylan Pharmaceuticals, Inc. ("Mylan"), in its memorandum in opposition to the motion to dismiss (at p. 19), cites a number of litigations in which Merck has been involved (see Tab D to Declaration of William A. Rakoczy submitted in support of Mylan's opposition). Of the cases in that list, 33 were ANDA cases and of those 33, only one, the Dr. Reddy's case, was filed

after the 45 day window had closed.

3. On September 28, 2005 Merck received an email message from counsel for Mylan offering to dismiss the complaint in this case if Merck would grant Mylan a covenant not to sue. A copy of that e-mail message is attached at Tab A.

4. On October 5, 2005, counsel for Merck sent a letter to Mylan in reply to their e-mail message of September 28, 2005, informing Mylan that, since, under applicable precedent, the declaratory judgment action should never have been filed, it was inappropriate for Mylan to request consideration from Merck as a condition for dismissing it. Mylan was invited to dismiss the case voluntarily. A copy of this letter is attached at Tab B.

5. On October 11, 2005, counsel from Mylan sent a reply letter to counsel for Merck in response to Merck's invitation stating that Mylan would not agree to any dismissals without the requested covenant and stipulations from Merck. A copy of this letter is attached at Tab C.

6. The patents mentioned in Mylan's complaint are those that have been identified in the Orange Book with respect to Merck's PROSCAR® product and Mylan's ANDA seeks only to obtain approval to market a generic version of that product.

7. There is one U.S. Patent listed in the Orange book for both the PROSCAR® and PROPECIA® products. Merck did not sue Dr. Reddy's on that patent.

8. The only suit Merck brought on any of its finasteride patents was against Dr. Reddy's and that suit was on different patents from those certified against by Mylan. In addition, Dr. Reddy's was seeking approval to market a generic version of Merck's PROPECIA® product, which is different from Merck's PROSCAR® product, a generic version of which Mylan is seeking to market.

I declare under penalty of perjury that the foregoing is true and correct.

October 26, 2005

Mary J. Morry

EXHIBIT A

Downey, Brian

From: William A. Rakoczy [wrakoczy@rmmslegal.com]
Sent: Wednesday, September 28, 2005 12:37 PM
To: Morry, Mary J.; Murray, Edward W (LEGAL)
Cc: Christine Siwik; Amy D. Brody; rbaechtold@fchs.com
Subject: Mylan v. Merck, No. 05-1416 (MDPA)---CONFIDENTIAL

Importance: High


Merck Covenant and Stipulation...


Proposed Dismissal Order.DOC

OLE_LINK4OLE_LINK3CONFIDENTIAL ? Provided Pursuant to Fed. R. Evid. 408

Dear Ed and Mary:

In view of the upcoming Joint Case Management Plan and status conference with the Court, we attach for your consideration a proposed covenant and stipulation as well as a proposed dismissal order for resolving this litigation.

If Merck will agree to the proposed stipulation and covenant, Mylan will agree to entry of the proposed order dismissing this litigation. Otherwise, Mylan intends to proceed with discovery and opposing Merck's motions to dismiss. Based on Merck's briefs, if Merck truly believes that Mylan has no reason to fear litigation from Merck, then we trust that we can resolve this matter with the attached stipulation and order.

Please let us know your thoughts. We would like to resolve this issue in advance of filing the Joint Case Management Plan if possible.

If you would like to discuss this issue or have any questions, please do not hesitate to call.

Best regards,

William A. Rakoczy

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IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA
HARRISBURG DIVISION

MYLAN PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	Case No. 05-cv-01416
v.	)	(Judge Sylvia H. Rambo)
	)	
MERCK & CO., INC.,	)	
	)	
Defendant.	)	

COVENANT NOT TO SUE AND STIPULATION OF NON-INFRINGEMENT OF U.S. PATENT NOS. 5,886,184; 5,942,519; AND 6,046,183

WHEREAS, Merck & Co., Inc. ("Merck") owns all right, title and interest in U.S. Patent No. 5,886,184 ("the '184 patent"), expiring on or about November 19, 2012; U.S. Patent No. 5,942,519 ("the '519 patent"), expiring on or about October 23, 2018; and U.S. Patent No. 6,046,183 ("the '183 patent"), expiring on or about March 20, 2011.

WHEREAS, pursuant to 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5), Mylan Pharmaceuticals Inc. ("Mylan") filed the present declaratory judgment action against Merck seeking a judicial declaration that the '184, '183, and '519 patents will not be infringed by the Finasteride Tablets 5 mg that are the subject of and described in Mylan's Abbreviated New Drug Application ("ANDA") No. 77-578 submitted to the U.S. Food and Drug Administration.

WHEREAS, pursuant to a confidentiality agreement, Mylan provided Merck with confidential documents from Mylan's ANDA No. 77-578 and samples of Mylan's proposed Finasteride Tablets 5 mg.

WHEREAS, based on Merck's confidential review of Mylan's proposed product and ANDA documents, Merck will stipulate to non-infringement of the '184, '183, and '519 patents and grant Mylan a covenant not to sue with respect to such patents.

NOW THEREFORE, Merck hereby stipulates, agrees and covenants as follows:

1. Merck unconditionally agrees and stipulates that the Finasteride Tablets 5 mg that are the subject of and described in Mylan's ANDA No. 77-578 do not infringe, and if imported, manufactured, used, sold or offered for sale in the United States would not infringe, any claim of Merck's '184, '183, and '519 patents.

2. Merck unconditionally represents, stipulates, agrees, and covenants that it will not sue Mylan for infringement of, or otherwise assert or enforce, Merck's '184, '183, and '519 patents based on the importation, manufacture, use, sale, or offer for sale of the Finasteride Tablets 5 mg that are the subject of and described in Mylan's ANDA No. 77-578.

Dated: September __, 2005.

MERCK & CO., INC.

_____

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Attorneys for Merck & Co., Inc.

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA
HARRISBURG DIVISION

MYLAN PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	Case No. 05-cv-01416
v.	)	(Judge Sylvia H. Rambo)
	)	
MERCK & CO., INC.,	)	
	)	
Defendant.	)	

ORDER

Upon consideration of the motion to dismiss of Merck & Co., Inc. ("Merck"), Merck's stipulation of non-infringement, and Merck's covenant not to sue Mylan Pharmaceuticals Inc. ("Mylan") for infringement of the patents-in-suit, the Court hereby grants Merck's motion and dismisses Mylan's Complaint for declaratory judgment for lack of subject matter jurisdiction, as follows:

1. Merck holds approved New Drug Application ("NDA") No. 20-180 for Proscar® (Finasteride) Tablets 5 mg.

2. Merck owns several patents relating to finasteride, including: U.S. Patent No. 4,760,071 ("the '071 patent"), expiring on or about June 19, 2006; U.S. Patent No. 5,886,184 ("the '184 patent"), expiring on or about November 19, 2012; U.S. Patent No. 5,942,519 ("the '519 patent"), expiring on or about October 23,

2018; and U.S. Patent No. 6,046,183 ("the '183 patent"), expiring on or about March 20, 2011.

3. Merck has listed the '071, '184, '519, and '183 patents in the U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), in connection with approved NDA No. 20-180 for Proscar® (Finasteride) Tablets 5 mg.

4. Mylan has submitted Abbreviated New Drug Application ("ANDA") No. 77-578 to FDA seeking approval to manufacture, use, and sell a generic version of Finasteride Tablets 5 mg prior to the expiration of Merck's '184, '519, and '183 patents.

5. In a letter dated April 26, 2005, Mylan sent Merck the requisite notice of Mylan's ANDA No. 77-578 for Finasteride Tablets 5 mg, together with the detailed factual and legal basis for Mylan's Paragraph IV Certification to the '184 and '183 patents. Mylan's notification letter included an offer of confidential access to Mylan's ANDA No. 77-578 so that Merck could evaluate whether an infringement action could be brought within forty-five (45) days of receiving Mylan's notification. Merck accepted Mylan's offer and requested access to certain parts of Mylan's ANDA No. 77-578 as well as samples of Mylan's proposed Finasteride Tablets 5 mg.

6. On June 2, 2005, pursuant to a revised offer of confidential access dated May 25, 2005, Mylan provided Merck with confidential documents from Mylan's ANDA No. 77-578 and samples of Mylan's proposed Finasteride Tablets 5 mg.

7. Merck did not sue Mylan for infringement within forty-five (45) days of receiving Mylan's notification letter.

8. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5), Mylan filed the present declaratory judgment action against Merck seeking a judicial declaration that the '184, '183, and '519 patents will not be infringed by the Finasteride Tablets 5 mg that are the subject of Mylan's ANDA No. 77-578.

9. By stipulation filed with the Court, Merck has unconditionally agreed and stipulated that the Finasteride Tablets 5 mg that are the subject of and described in Mylan's ANDA No. 77-578 do not infringe, and if imported, manufactured, used, sold, or offered for sale in the United States would not infringe, any claim of Merck's '184, '183, and '519 patents.

10. By stipulation filed with the Court, Merck also has unconditionally agreed, promised, and covenanted that it will not sue Mylan for infringement of, or otherwise assert or enforce, Merck's '184, '183, and '519 patents based on the importation, manufacture, use, sale, or offer for sale of the Finasteride Tablets 5 mg that are the subject of and described in Mylan's ANDA No. 77-578.

For the foregoing reasons, based on Merck's stipulation of non-infringement and covenant not to sue, the Court grants Merck's motion to dismiss and hereby dismisses this matter for lack of subject matter jurisdiction. Each party shall bear its own costs, expenses, and attorneys' fees.

_____

United States District Judge Sylvia H. Rambo

DATED: September __, 2005.

EXHIBIT B

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STEVAN J. BOSSES
DIRECT DIAL (212) 218-2257
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October 5, 2005

Via E-mail

William A. Rakoczy, Esq.
Rakoczy Molino Mazzochi Siwik LLP
6 West Hubbard Street
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Chicago, Illinois 60610

Re: Mylan Pharmaceuticals Inc. v. Merck & Co., Inc

Dear Mr. Rakoczy:

I write in response to your email message directed to Edward W. Murray, Esq. and Mary J. Morry, Esq. of our client, Merck & Co. Inc. ("Merck"). As Merck is represented by outside counsel, for all future purposes, please direct all correspondence regarding this case either to Bob Baechtold or me.

As you know, the Court of Appeals for the Federal Circuit, in *Teva Pharmaceuticals USA Inc. v. Pfizer*, 395 F.3d 1324, 1333 (Fed. Cir. 2005) held that a patentee has no obligation to give a covenant not to sue and that its refusal to do so does not create the reasonable apprehension that is the necessary predicate to federal court jurisdiction.

It is Merck's position, as fully explained in our motion papers and the precedent we cited, that your declaratory action should not have been filed in the first place, so your requesting some consideration from Merck as a condition for dismissing it is inappropriate. We invite you to dismiss the case voluntarily.

Very truly yours,
FITZPATRICK, CELLA, HARPER & SCINTO

Steven J. Bosses

SJB:sw

cc: Ed Murray (via e-mail)
Mary Morry (via e-mail)
Brian Downey (via e-mail)

EXHIBIT C

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October 11, 2005

VIA E-mail

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Re: *Mylan Pharmaceuticals Inc. v. Merck & Co., Inc.*
No. 05-cv-01416 (M.D. Pa.) (Rambo, J.)

Dear Mr. Bosses:

On behalf of Mylan Pharmaceuticals Inc., we write in response to your letter, dated October 5, 2005, rejecting Mylan's offer to resolve this matter amicably. We obviously disagree with the characterizations in your letter and do not believe that they merit a response. As to your "invitation," Mylan will not agree to any dismissal without the requested covenants and stipulations from Merck, which we trust would not be a problem if Merck truly had no intention to enforce the patents.

Very truly yours,

RAKOCZY MOLINO MAZZOCHI SIWIK LLP

William A. Rakoczy /AOB

William A. Rakoczy

cc (via e-mail): Robert Baechtold
Ed Murray
Mary Morry
Brian Downey
Charles Rubendall

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA
HARRISBURG DIVISION

MYLAN PHARMACEUTICALS INC., Plaintiff,	:	
v.	:	Civil Action No. 05-cv-1416 (Judge Rambo)
MERCK & CO., INC., Defendant.	:	

DECLARATION OF STEVAN J. BOSSES UNDER 28 U.S.C § 1746 IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

I, Stevan J. Bosses, declare under penalty of perjury that:

1. I make this declaration in support of the motion of defendant, Merck & Co., Inc. ("Merck") to dismiss plaintiff's complaint for declaratory judgment.

2. I am an attorney admitted to practice and in good standing in New York. I am also admitted to this Court pro hac vice. I am a partner in the firm of Fitzpatrick, Cella, Harper & Scinto, attorneys for Merck in this litigation.

3. I have also been admitted to practice before the United States Supreme Court, the United States Courts of Appeal for the Second, Third and

Federal Circuits and of the United States District Courts for the Southern, Eastern and Northern Districts of New York, the Eastern District of Michigan and the Western District of Wisconsin.

4. I have either personal knowledge of the facts set forth in this declaration, or I have verified their accuracy by reviewing appropriate records.

5. Attached hereto behind Tab A is a true and correct copy of the "Brief of the Generic Pharmaceutical Association as Amicus Curiae in Support of Plaintiff's Motion for a Preliminary Injunction" dated August 30, 2005 and filed in Teva Pharmaceuticals USA, Inc. v. Food and Drug Administration, Michael O. Leavitt, and Lester M. Crawford, Civil Action No. 1:05-CV-01469 (JDB) in the U.S. District Court for the District of Columbia.

I declare under penalty of perjury that the foregoing is true and correct.

October 21, 2005

Stevan J. Bosses

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC. *Plaintiff,* *v.* FOOD AND DRUG ADMINISTRATION, MICHAEL O. LEAVITT, and LESTER M. CRAWFORD, *Defendants.*	Civil Action No. 1:05-CV-01469 (JDB)

MOTION OF THE GENERIC PHARMACEUTICAL ASSOCIATION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

The Generic Pharmaceutical Association ("GPhA"), by its undersigned counsel, respectfully requests the entry of an order granting it leave to file the accompanying *amicus curiae* brief in support of Plaintiff's pending motion for a preliminary injunction, which GPhA understands to have been converted to a motion for summary judgment. In support of this request, GPhA relies upon the accompanying memorandum of points and authorities. A proposed form of order is respectfully submitted herewith.

WHEREFORE, for the reasons set forth in the accompanying memorandum of points and authorities, GPhA respectfully requests leave to file the accompanying proposed brief *amicus curiae.*

Respectfully submitted,

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DC Bar No. 298331
WILLKIE FARR & GALLAGHER LLP
1875 K Street, NW
Washington, DC 20006-1238
Telephone: 202-303-1000
Facsimile: 202-303-2000

Counsel for *Amicus Curiae*
The Generic Pharmaceutical Association

Dated: Washington, DC
30 August 2005

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC. *Plaintiff,* *v.* FOOD AND DRUG ADMINISTRATION, MICHAEL O. LEAVITT, and LESTER M. CRAWFORD, *Defendants.*	Civil Action No. 1:05-CV-01469 (JDB)

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF THE MOTION OF THE GENERIC PHARMACEUTICAL ASSOCIATION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

The Generic Pharmaceutical Association ("GPhA"), by its undersigned counsel, respectfully submits this memorandum of points and authorities in support of its motion for leave to file an *amicus curiae* brief in support of Plaintiff's pending motion for a preliminary injunction, which GPhA understands to have been converted to a motion for summary judgment. GPhA's purpose in seeking leave to file its *amicus* brief is to give the Court an industry-wide perspective on the Hatch-Waxman question presented by this case.

GPhA is a voluntary, non-profit association comprised of more than 140 manufacturers and distributors in the generic pharmaceutical industry, accounting for more than 90 percent of the prescriptions dispensed in the United States every year. GPhA's members provide safe and cost-effective medicines that are bioequivalent to, and have the same therapeutic value as, their

brand-name counterparts. Products produced and distributed by GPhA members improve the health of Americans while cutting annual health care costs by billions of dollars.

This case concerns fundamental questions regarding the scope and effect of the 180-day exclusivity period provided by Congress as an incentive to generic drug makers to assume the risks and burdens of litigation to challenge questionable patents blocking competitive provision of prescription drugs. GPhA has a strong interest in ensuring the preservation of the 180-day exclusivity provision. GPhA has no particular interest in whether one company or another enjoys a right to 180-day exclusivity for pravastatin sodium or any particular generic drug. GPhA's members include both first filers and subsequent filers, and indeed, it is typically the case that what goes around comes around: A generic company that has filed the first abbreviated new drug application for one drug will be a subsequent filer for other drugs. GPhA has a strong interest, however, in ensuring the preservation of the Hatch-Waxman's incentive scheme, which benefits the industry as a whole, as well as consumers.

GPhA believes that the Food and Drug Administration's action in this case threatens the statutory balance between the rights of first and subsequent filers, and thereby may adversely affect the millions of consumers and insurers who rely upon affordable generic drugs. In enacting the Hatch-Waxman Act, Congress provided for a defined and narrow set of conditions that would trigger the 180-day exclusivity period, and in particular, determined that a judicial decision would trigger exclusivity only when it contained a holding that the patent was invalid of not infringed. Not only does the FDA action, if upheld, violate the language of Hatch-Waxman, but it also would fundamentally disrupt the incentive system embodied in the Act, through which Congress has ensured that generic manufacturers will challenge potentially blocking patents in order to bring the generic products to market as soon as practicable. The FDA's action, while

technically issued under the pre-amended Hatch-Waxman Act, threatens to undermine generic entry under the recently revised Medicare Modernization Act of 2003 as well. Accordingly, GPhA seeks the opportunity to urge this Court to enter a judgment setting aside the FDA action.

By reflecting the collective experience and judgments of its members, GPhA believes that it brings to this case a unique and valuable perspective on the issues before the Court. Among other things, GPhA's brief makes clear that this is not a parochial dispute among generic pharmaceutical companies but a matter with broad, industry-wide implications, the resolution of which may have important effects on competition in the pharmaceutical industry and thus on consumers and insurers.

This Court's local rules do not establish a deadline for the submission of briefs *amicus curiae* in these circumstances. GPhA is making this motion and submitting its brief in advance of the 25 September 2005 hearing on Plaintiff's motion and as promptly as reasonably possible given the need to obtain the necessary approvals for such a brief within its governance structure.

For these reasons and such other and further reasons as may become apparent upon full consideration of GPhA's motion, GPhA respectfully requests that the Court enter an order granting GPhA's motion for leave to file the accompanying brief *amicus curiae*.

Dated: Washington, DC
30 August 2005

Respectfully submitted,

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Counsel for *Amicus Curiae*
The Generic Pharmaceutical Association

Teva Pharmaceuticals USA, Inc. v. Food & Drug Administration, et al.
No. 1:05-CV-01469 (JDB)

CERTIFICATE OF SERVICE

I hereby certify that, on 30 August 2005, copies of the foregoing motion, memorandum of points and authorities, proposed order, certificate of counsel, and proposed brief of *amicus curiae* were sent by First Class United States Mail, postage prepaid, to each of the following:

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Kate Cumming Beardsley, Esq.
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Theodore Case Whitehouse

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC. *Plaintiff,* *v.* FOOD AND DRUG ADMINISTRATION, MICHAEL O. LEAVITT, and LESTER M. CRAWFORD, *Defendants.*	Civil Action No. 1:05-CV-01469 (JDB)

[PROPOSED] ORDER GRANTING THE MOTION OF THE GENERIC PHARMACEUTICAL ASSOCIATION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

This matter is before the Court on the motion of the Generic Pharmaceutical Association ("GPhA") for leave to file an *amicus curiae* brief in support of Plaintiff's pending motion for a preliminary injunction (which has been converted to a motion for summary judgment). Upon consideration of the motion, any response thereto, and the record herein, it is this _____ day of September, 2005,

ORDERED that GPhA's motion be, and hereby is, GRANTED.

Hon. John D. Bates
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC. *Plaintiff*, *v.* FOOD AND DRUG ADMINISTRATION, MICHAEL O. LEAVITT, and LESTER M. CRAWFORD, *Defendants*.	Civil Action No. 1:05-CV-01469 (JDB)

CERTIFICATE REQUIRED BY LOCAL CIVIL RULE 7.1
SUBMITTED ON BEHALF OF PROPOSED *AMICUS CURIAE*
GENERIC PHARMACEUTICAL ASSOCIATION

The undersigned counsel of record for proposed *amicus curiae* Generic Pharmaceutical Association ("GPhA") certifies that, to the best of his knowledge and belief, GPhA is a trade association and has no parents, subsidiaries, or affiliates that have any outstanding securities in the hands of the public. These representations are made in order that judges of this Court may determine the need for recusal.

Dated: Washington, DC
30 August 2005

Respectfully submitted,

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Facsimile: 202-303-2000

Counsel for *Amicus Curiae*
The Generic Pharmaceutical Association

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC. *Plaintiff*, *v.* FOOD AND DRUG ADMINISTRATION, MICHAEL O. LEAVITT, and LESTER M. CRAWFORD, *Defendants*.	**Civil Action No. 1:05-CV-01469 (JDB)**

BRIEF OF THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

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202-303-1000

Counsel for *Amicus Curiae*
The Generic Pharmaceutical Association

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OTHER AUTHORITIES

INTRODUCTION

The Generic Pharmaceutical Association ("GPhA") respectfully submits this *amicus curiae* brief in support of Plaintiff's pending motion for a preliminary injunction, which GPhA understands to have been converted to a motion for summary judgment. GPhA's purpose in filing this brief is to give the Court an industry-wide perspective on the Hatch-Waxman question presented by this case.

GPhA is a voluntary, non-profit association comprised of more than 140 manufacturers and distributors in the generic pharmaceutical industry, accounting for more than 90 percent of the prescriptions dispensed in the United States every year. GPhA's members provide safe and cost-effective medicines that are bioequivalent to, and have the same therapeutic value as, their brand-name counterparts. Products produced and distributed by GPhA members improve the health of Americans while cutting annual health care costs by billions of dollars.

GPhA has a strong interest in ensuring the preservation of the 180-day exclusivity provision enacted by Congress. GPhA has no particular interest in whether one company or another enjoys a right to 180-day exclusivity for pravastatin sodium or any particular generic drug. GPhA's members include both first filers and subsequent filers, and indeed, it is typically the case that what goes around comes around: A generic company that has filed the first abbreviated new drug application for one drug will be a subsequent filer for other drugs. GPhA has a strong interest, however, in ensuring the preservation of the Hatch-Waxman Act's carefully crafted incentive scheme, which benefits the industry as a whole, as well as consumers.

GPhA believes that the Food and Drug Administration's action in this case threatens the statutory balance between the rights of first and subsequent filers, and thereby may adversely affect the millions of consumers and insurers who rely upon affordable generic drugs. In enacting the Hatch-Waxman Act, Congress provided for a defined and narrow set of conditions

that would trigger the 180-day exclusivity period, and in particular, determined that a judicial decision would trigger exclusivity only when it contained a holding that the patent was invalid or not infringed. Not only does the FDA's decision conflict with the D.C. Circuit's construction of the statute and violate the language of Hatch-Waxman, but it also would fundamentally disrupt the carefully calibrated incentive system embodied in the Act, through which Congress has ensured that generic manufacturers will challenge potentially blocking patents in order to bring the generic products to market as soon as practicable. The FDA's action, while technically issued under the pre-amended Hatch-Waxman Act, threatens to undermine generic entry under the recently revised Medicare Modernization Act of 2003 as well. Accordingly, GPhA urges this Court to enter a judgment setting aside the FDA action.

FACTS

In this litigation, Teva Pharmaceuticals USA, Inc. ("Teva") challenges the FDA's conclusion that the Hatch-Waxman 180-day exclusivity period may be triggered by a district court decision that does not include a holding—explicit or implicit—as to invalidity, non-infringement, or unenforceability.

Teva was the first generic manufacturer to file an abbreviated new drug application ("ANDA") for generic pravastatin sodium. Apotex, Inc. also filed an ANDA for generic pravastatin sodium. Bristol-Myers Squibb ("BMS"), which sells pravastatin sodium under the name Pravachol®, did not concede the invalidity, non-infringement, or unenforceability of its patents, notwithstanding the filing of several ANDAs indicating an intent to bring the generic substitute to market. *See* Mem. of Law in Supp. of Def.'s Mot. to Dismiss Pls.' Compl., *Apotex, Inc. v. Bristol-Myers Squibb Co.*, No. 04 CV 2922 (S.D.N.Y. July 23, 2004) (Pl.'s Mem. in Supp. of Application for a Prelimin. Inj. ("PI Mem.") Ex. C). Apotex then brought a declaratory judgment action against BMS under Section 505(j)(5)(C)(i) of the Hatch-Waxman Act. After

Apotex filed its declaratory judgment action, but before the court ruled on BMS's motion to dismiss, the court approved the parties' stipulated dismissal, which was based on "BMS's pre-Complaint representations that it has no intention to sue Apotex." *Apotex, Inc. v. BMS,* No. 04 CV 2922 (S.D.N.Y. July 23, 2004) (stipulation and order granting dismissal) (PI Mem. Ex. E at 3). The stipulated dismissal did not include any findings, nor did it enter a holding as to the validity, infringement, or enforceability of the pravastatin patents. *Id.*

On June 28, 2005, the FDA issued a letter stating that the district court's entry of the stipulated dismissal had triggered the 180-day exclusivity period for generic pravastatin sodium, and that the exclusivity period had expired in February 2005. *See* June 28, 2005 Letter from Director of the FDA Office of Generic Drugs Gary Buehler to Philip Erickson ("FDA Letter") (PI Mem. Ex. A).

ARGUMENT

I. THE FDA'S CONCLUSION THAT EXCLUSIVITY MAY BE TRIGGERED BY A STIPULATED DISMISSAL WITHOUT A HOLDING ON THE MERITS OF THE PATENT CONTRAVENES BOTH THE TEXT AND THE PURPOSE UNDERLYING THE HATCH-WAXMAN ACT.

The FDA's conclusion that a stipulated dismissal that does not include a holding as to invalidity, non-infringement, or unenforceability triggers 180-day exclusivity is an improper interpretation of the cases decided under the Hatch-Waxman Act (as Teva argued) and is also in conflict with the clear language of the Hatch-Waxman Act. There, Congress specified which types of court decisions—those holding the underlying patents to be invalid or not infringed—could trigger exclusivity. Although it could have chosen to do so, Congress did not provide that any and all court decisions could trigger exclusivity. Thus, only those court decisions—regardless of who is a party to the court decisions—that meet the congressionally-specified criteria can trigger the running of the 180-day exclusivity period.

More significantly, the FDA's conclusion, if upheld, would unsettle the incentive system of the Hatch-Waxman Act. Congress included the 180-day exclusivity provision, and specified when the attending benefits would be triggered, to ensure that the promise of exclusivity would provide generic companies with the incentive to come to market as soon as possible. By disregarding the limitation on which court decisions can trigger exclusivity and allowing *any* court decisions, including those that do not adjudicate and clear void or blocking patents, the FDA has cut the legs out from under what Congress determined to be the appropriate incentive for bringing generic products to market. As a result of the FDA's action, manufacturers are free to bring "challenges" that, in fact, are designed to do no more than run out the clock on exclusivity before the generic can ever come to market. The result under both the pre-amended Hatch-Waxman Act and the MMA will be to discourage generic manufacturers from competing to get exclusivity in the first place, given the likelihood of their losing it before ever receiving its benefits.

A. The 180-Day Exclusivity Period, As It Was Established By Congress, Is Essential To The Balance Of Interests And Incentives In The Hatch-Waxman Act.

Generic pharmaceuticals reduce healthcare costs by providing consumers and insurers with access to safe and lower cost pharmaceuticals, often before the patents on the branded versions of those pharmaceuticals expire. Because the principal barrier to early generic entry is the lawful monopoly granted to holders of drug patents, Congress passed the Hatch-Waxman Act of 1984, which reflects a legislative compromise between the interests of brand and generic pharmaceutical manufacturers that encourages and hastens generic drug entry. *See generally* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585

(1984); *see* 21 U.S.C. §§ 301 *et seq.*[1]; H. Rep. No. 98-857, at 14-15 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48 (the statute seeks to "make available more low cost generic drugs" and "to create an incentive for increased expenditures for research and development of certain products which are subject to premarket government approval").

While validating, and even extending, protections for branded pharmaceuticals, Hatch-Waxman reduced barriers to generic entry by establishing an expedited approval process, known as an ANDA, within the FDA. Filing an ANDA, and providing the requisite certification to the patent holder (known as a Paragraph IV certification), is the first step a generic manufacturer takes on the road to challenging the "thicket" of potentially invalid or non-infringed patents that can block generic entry. Because the first company to file a complete ANDA is necessarily the first company to put the patent holder on notice that a generic product will be marketed prior to the expiration of the pertinent patents, the first ANDA filer bears the primary risk of being sued by the patent holder and defending against expensive and time-consuming patent litigation. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (2000). Congress created significant incentives in the Hatch-Waxman Act to encourage generic drug manufacturers to assume that risk and file ANDAs with Paragraph IV certifications.

The key incentive that Congress included for generic manufacturers is the promise of 180 days of marketing exclusivity for the first ANDA filer, before other generic manufacturers can market their products. During that 180-day period, consumers and insurers save money because of the availability of the generic alternative, and the first-filing generic drug company can recover for the risk and expense it incurred by filing the Paragraph IV ANDA in the first place.

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[1] The Hatch-Waxman Act was amended by the Medicare Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003), however the old Act governs this matter because the pertinent ANDA was filed before the new Act took effect.

Significantly, Hatch-Waxman bestows exclusivity on the first company to file a complete ANDA, not on the first company to bring a legal challenge to the brand manufacturer's patents, thus encouraging generic manufacturers to move their products through the FDA approval pipeline, rather than encouraging them to engage in intra-industry litigation.

It is this cycle, of which the 180-day exclusivity period is a considered and integral part, that results in generic pharmaceuticals coming to market as soon as possible. *See* FDA, *Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day* 3 (July 2003), http://www.fda.gov/cder/guidance/5710fnl.pdf. *See also* FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. Two decades after the Hatch-Waxman Act, generics now represent more than half of the total prescriptions dispensed in the United States but less than 10 percent of the total dollar amount spent on prescription drugs. *See* GPhA, *Generic Pharmaceuticals: Getting More and Spending Less*, http://www.gphaonline.org/policy/pdf/statement1.pdf.

In 2003, Congress amended the Hatch-Waxman Act as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Pub. L. No. 108-173, 117 Stat. 2066 (2003). In the MMA, Congress added to the attraction of the 180-day exclusivity period by creating a shared exclusivity provision. Under the new Act and rules, exclusivity is "shared" among those companies that file a complete ANDA on the first day of filing. *See* FDA Guidance for Industry, at 4-5. Thus, Congress very recently recognized and validated the importance of incentivizing generic manufacturers to bring their products to market as soon as possible. As with the earlier Act, Congress again chose to grant market exclusivity to those companies that are quick to meet the substantive requirements of filing an ANDA with the FDA, as opposed to

granting it to those companies that are quick to engage in litigation with the branded manufacturer.

B. The FDA Has Disregarded The Congressionally Mandated Restrictions On What Triggers 180-Day Exclusivity.

When the 180-day exclusivity period begins, the lawful monopoly enjoyed by a branded manufacturer ends. Because generic manufacturers cannot sell their products in violation of valid patents, Congress specified that the 180-day exclusivity period will not begin until all legitimate barriers to generic entry have been adjudicated and cleared. The FDA's approach to the stipulated dismissal in *Apotex, Inc. v. BMS*, however, throws open the doors to generic entry absent *any* such determination. Moreover, by disregarding the Hatch-Waxman Act's clear requirement that a triggering court decision hold that the certified patent is invalid or not infringed, the FDA will fuel precisely the type of Hatch-Waxman Act gamesmanship that Congress condemned when it reviewed the Act and passed the MMA.

Under Hatch-Waxman, the first possible trigger of the exclusivity period is "the date . . . of the first commercial marketing of the drug under the [ANDA]." 21 U.S.C. § 355(j)(5)(B)(iv)(I) (1994). This triggering provision is not at issue here, because an unchallenged sister patent for Pravachol® does not expire until early 2006. The second possible trigger is "the date of a decision of a court . . . ***holding*** the patent which is the subject of the [Paragraph IV] certification to be ***invalid*** or not ***infringed*** . . . ." *Id.* § 355(j)(5)(B)(iv)(II) (emphasis supplied). In other words, only after the patent holder's asserted monopoly has been adjudicated and determined to be either invalid or not infringed can the exclusivity period start to run. Congress thus required a demonstration that the pertinent patent is not a legal barrier to generic competition.

The FDA is well aware of the importance of resolving the patent dispute in advance of generic entry. By regulation, the FDA also allows a court decision holding a patent "unenforceable" to trigger the exclusivity period. 21 C.F.R. § 314.107(e)(1) (1999). This is because the "FDA believed that ***for the 180-day exclusivity to have real meaning*** for the eligible ANDA applicant, ***the court decision triggering the exclusivity must be the one that finally resolves the patent infringement litigation*** related to the ANDA." *See* FDA Center for Drug Evaluation & Research, *Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* 2 (Mar. 2000) (emphasis supplied), http://www.fda.gov/cder/guidance/3659fnl.pdf. Thus, in the past and present iterations of the statute, exclusivity triggers have been tied to the expiration of the brand's legal monopoly.

Here, the FDA concluded that a district court's stipulated dismissal triggered the 180-day exclusivity period. In *Apotex, Inc. v. Bristol-Myers Squibb Co.*, No. 1:04-CV-2922 (S.D.N.Y.), the district court entered as an order the joint stipulation of the parties that they ***disagreed*** over the validity of the patent, but that there was no controversy since BMS, the patent holder, had represented that it did not intend to sue. *See* PI Mem. Ex. E. The court dismissed the action without prejudice based solely on absence of a litigation threat. *See id.* The court did not enter any findings or holding as to the invalidity, noninfringement, or unenforceability of the patent. *See id.* According to the FDA, the stipulated dismissal "qualified as a court decision under section 505(j)(5)(B)(iv)(II), triggering the running of 180-day exclusivity."

The FDA took this position even though the district court did not provide the requisite holding as to invalidity, non-infringement, or unenforceability of the underlying patents. If that is correct, then the district court's approval of ***any*** dismissal would constitute a triggering

"decision of a court" regardless of what it held, or even if it held nothing at all. Had Congress intended for stipulated orders such as settlements or consent decrees to be court decision triggers, it could have expressly said so, as it did in the MMA. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB) (2005). But Congress provided that a judgment in an action would constitute a judicial trigger only where there was a "decision of a court ... ***holding***" a particular result—invalidity or noninfringement—about the patent. The FDA cannot, by administrative fiat, read this critical, limiting language out of the Hatch-Waxman Act.

In 2003, Congress took the opportunity to reiterate in the MMA the importance of limiting which court decisions can trigger exclusivity. In a provision that is retroactive to filings under the original act such as this one, Congress defined a "decision of a court" under the original Act as "a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken." Pub. L. No. 108-173 § 1102(b)(3). In other words, Congress determined that exclusivity should not, and cannot, run until it is certain that the patent can no longer (barring unlikely Supreme Court review and reversal) be a legal barrier to the entry of generic alternatives into the market.[2]

Of course, Congress could have indicated that any type of court decision could qualify as a "decision of a court," just as Congress could have chosen to apply this provision only prospectively. Congress, however, chose to limit qualifying court decisions—under both the old and the new Acts—to those that definitively adjudicate the merits of the underlying patent controversy, eliminating any confusion over the types of adjudications that might trigger exclusivity by singling out certain types of court decisions and excluding others. Thus, Congress

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[2] *See also* Pub. L. No. 108-173 § 1101(a)(2)(A)(II)(aa) (Congress provided that a settlement can trigger the 180-day exclusivity period, but only where the patent holder indicates in the settlement that the patent is not infringed or invalid.)

reinforced in its Amendments the policy that patent invalidity or noninfringment, and thus removal of the patent barrier to legal entry into the market of the generic drug, is the proper trigger for exclusivity.

Even though this case is to be decided under the old Act, the FDA's position threatens the exclusivity benefit under the MMA as well. The FDA has disregarded the clear limits set by Congress in the old Act on proper triggers of the 180 day periods. The MMA, like the previous provision, also includes specific, congressionally-mandated limits on what can trigger the 180 days: unappealable final judgments, entry of settlement orders, and consent decrees that indicate on the merits that "the patent is invalid or not infringed." 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(AA)-(CC). If the FDA is allowed to ignore the limits set forth in the old Act, the agency easily could use such precedent to ignore these limits (or other unrelated provisions) in the MMA as well.

C. The FDA Action Undermines The Value of 180-Day Exclusivity, The Key Incentive That Congress Established To Bring Generic Pharmaceuticals To Market, To The Detriment Of Consumers And Insurers.

Congress crafted and calibrated the 180-day exclusivity provision to ensure that the generic pharmaceutical industry is incentivized to develop and bring to market generic drugs. In marked contrast to the Hatch-Waxman Act—both in its original form and as amended by the MMA—the FDA's position inevitably will dis-incentivize the industry, chilling the very patent challenges that the Hatch-Waxman Act was designed to induce.

The FDA's position undermines the market exclusivity incentive because it permits exclusivity to be triggered by any kind of court decision, including those that do not in any way resolve the underlying patent dispute. Congress created the judicial-decision trigger to ensure that, once the legal barrier to generic competition has been removed, the first generic drug company will have a strong incentive to come to market as quickly as possible. If exclusivity

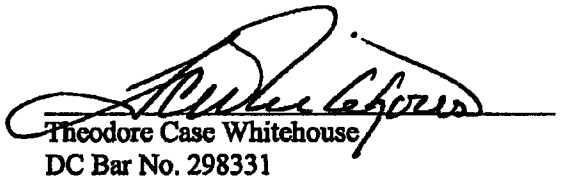
begins to run before the underlying patent challenge is resolved, then exclusivity could expire—as in the pravastatin sodium case—before any generic drug company could bring its product to market. If the judicial-decision trigger can be subject to such manipulation, then the 180-day incentive provision can no longer serve the purpose of encouraging generic companies to file the first ANDA challenge and begin the process of bringing the generic alternative to market. By allowing court-decisions that do not resolve the merits of patent disputes to trigger and run down the exclusivity period, the FDA has markedly undercut the value of the incentive that Congress established to encourage generic market entry.

The inevitable and cumulative result of the FDA's decision will be to discourage generic manufacturers from competing for exclusivity by filing early ANDAs. The erosion of the incentive effects intended to be achieved by exclusivity will result in a collective action problem and massive opportunity costs for the entire industry. Rather than race to file ANDAs early and run the risk of costly patent litigation without the exclusivity benefit, generic manufacturers that would have filed early ANDAs could sit on the sidelines until another generic manufacturer challenges the brand patents and opens the gateway for generic entry. As the ANDA filings drop off, the rate at which generic pharmaceuticals come to market will also slow, harming the generic market, consumers, and insurers. Ultimately and ironically, the only companies that will benefit from the FDA's position are the brand-name companies: After 20 years of vibrant generic industry competition under Hatch-Waxman, the brands will be back in a world where their patents are not readily challenged before they expire because the primary incentive to challenge them has been eviscerated, consequently allowing the brands to enjoy their pharmaceutical monopolies longer, to the continuing detriment of the public.

CONCLUSION

For the foregoing reasons, GPhA respectfully requests that the Court vacate the Food and Drug Administration's decision and declare that a judicial dismissal for lack of subject-matter jurisdiction will not trigger the running of the statutory exclusivity when there is no implicit finding of invalidity or noninfringement.

Respectfully submitted,



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Dated: Washington, DC
30 August 2005

CERTIFICATE OF SERVICE

I hereby certify that on October 26, 2005, a copy of the foregoing was filed electronically and should be served upon the following individuals through the Court's Electronic Case Filing (ECF) system:

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